EXHIBIT 16

EXPERT REPORT

Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances

Prepared by
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List of Schedules

McKesson Corporation[148]	[redacted]
CVS[149]	
Walgreens[150]	

I have been asked to identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.[151] However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[152] *See* Methodology A above. Pursuant to *Masters,* "as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence" *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT1 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT1 jurisdictions.

IV. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

[148] *Id*. at 802.

[149] *Id*. at 847.

[150] *Id*. at 892.

[151] This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the distributor and manufacturer specific sections of this report.

[152] This approach does not take into consideration unusual pattern or frequency.

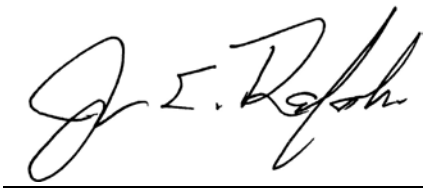
respect to the SOMs policies at Insys. However, Mr. Reimer's deposition has been stayed until after the criminal trial by the DOJ in the District of Massachusetts because Mr. Reimer is on the DOJ's witness list.

4. Nevertheless, deposition testimony by current Insys employees has confirmed that Insys failed to implement any SOM system or maintain any SOM protocols until 2018.[908]

5. This failure to conduct any sort of SOM process continued despite the fact that Insys was conscious that it habitually lost track of inventory in its downstream customers like Linden Care.[909] For other wholesalers where they did not receive inventory level reports, Insys estimated the levels. Significant differences between actual and estimated inventory levels often resulted. Many times, distributor purchases exceeded customer demand, a situation that creates a risk of diversion.

In my expert opinion, Insys failed to conduct any SOM process, even failing to track for orders of unusual size. The lack of any SOM program did not satisfy DEA requirements to detect and investigate suspicious orders. Insys failed to maintain effective controls to prevent diversion.

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.



James E. Rafalski

Date: April 15, 2019

[908] *See* Deposition of James Doroz at 53; 118; 251. *See* also Thomas Udicious Tr. at 19; 44.

[909] *See* James Doroz Tr. at 221.